

Status of Meeting: Open—June 21: 8:30–9:00 a.m.; Closed—Otherwise.

Contact: Heinz Sorer, Room 10-42, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857, (301) 443-2620.

Purpose: The Committee is charged with the initial review of applications for assistance from the National Institute on Drug Abuse for support of research and research training activities and makes recommendations to the National Advisory Council on Drug Abuse for final review.

Committee Name: Prevention and Epidemiology Subcommittee of the Alcohol Psychosocial Research Review Committee, NIAAA.

Date and Time: June 22–24: 9:00 a.m.

Place: Wyndham Bristol Hotel, 2430 Pennsylvania Avenue, NW., Washington, DC 20037.

Status of Meeting: Open—June 22: 9:00–9:30 a.m.; Closed—Otherwise.

Contact: Lenore Radloff, Room 16C-26, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857, (301) 443-6106.

Purpose: The Committee is charged with the initial review of applications for assistance from the National Institute on Alcohol Abuse and Alcoholism for support of research and research training activities and makes recommendations to the National Council on Alcohol Abuse and Alcoholism for final review.

Committee Name: Small Business Research Review Committee, NIMH.

Date and Time: June 27–28: 9:00 a.m.

Place: Holiday Inn Crowne Plaza, 1750 Rockville Pike, Rockville, MD 20852.

Status of Meeting: Open—June 27: 9:00–10:00 a.m.; Closed—Otherwise.

Contact: Bonnie Dwyer, Room 9C-05, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857, (301) 443-6470.

Purpose: The Committee is charged with the initial review of applications requesting support from the National Institute of Mental Health for small businesses involved in mental health research. Final review and recommendations are made from the National Advisory Mental Health Council.

Substantive information, summaries of the meetings, and rosters of committee members may be obtained as follows: Ms. Diana Widner, NIAAA Committee Management Officer, Room 16C-20, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, (301) 443-4375; Ms. Camillia Holland, NIDA Committee Management Officer, Room 10-42, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857, (301) 443-2620; Ms. Joanna Kieffer, NIMH Committee Management Officer, Room

9-105, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, (301) 443-4333.

Date: May 5, 1988.

Peggy W. Cockrill,

Committee Management Officer, Alcohol, Drug Abuse, and Mental Health Administration.

[FR Doc. 88-10480 Filed 5-10-88; 8:45 am]

BILLING CODE 4160-20-M

Food and Drug Administration

[Docket No. 88E-0104]

Determination of Regulatory Review Period for Purposes of Patent Extension; Ucephan™

AGENCY: Food and Drug Administration.
ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Ucephan™ and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension for a patent which claims that human drug product.

ADDRESS: Written comments and petitions should be directed to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Andrea E. Chamblee Office of Health Affairs (HFY-20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-1382.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) generally provides that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under that act, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug

product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product Ucephan™. Ucephan™ (10 percent sodium phenylacetate and 10 percent sodium benzoate) oral solution is indicated as adjunctive therapy for the prevention and treatment of hyperammonemia in the chronic management of patients with urea cycle enzymopathies involving partial or complete deficiencies of carbamylphosphate synthetase, ornithine transcarbamylase, or argininosuccinate synthetase. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Ucephan™ (U.S. Patent No. 4,284,647) from the Johns Hopkins University, and requested FDA's assistance in determining the patent's eligibility for patent term restoration. FDA, in a letter dated March 30, 1988, advised the Patent and Trademark Office that the human drug product had undergone a regulatory review period. The letter also stated that one of the active ingredients sodium phenylacetate, represented the first permitted commercial marketing or use, and that the other active ingredient sodium benzoate, did not represent the first permitted commercial marketing or use. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for Ucephan™ is 2,871 days. Of this time, 2,058 days occurred during the testing phase of the regulatory review period, while 813 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under section 505(i) of the Federal Food, Drug and Cosmetic Act became effective: February 14, 1980. The applicant claims the letter date, January 10, 1980, as the effective date of the first investigational new drug application (IND 17-123) related to the approved product. However, FDA records indicate that

IND 17-123 became effective 30 days after receipt, on February 14, 1980.

2. *The date of the application was initially submitted with respect to the human drug product under section 505(b) of the Federal Food, Drug, and Cosmetic Act:* October 2, 1985. The applicant claims September 30, 1985, as the date that a new drug application (NDA 19-530) for Ucephan™ was initially submitted. However, FDA did not receive NDA 19-530 until October 2, 1985.

3. *The date the application was approved:* December 23, 1987. FDA has verified the applicant's claim that NDA 19-530 was approved on December 23, 1987.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 730 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before July 11, 1988, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before November 11, 1988, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, Part 1, 98th Cong., 2d Sess., pp. 41-42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 27, 1988.

Stuart L. Nightingale,
Associate Commissioner for Health Affairs.
[FR Doc. 88-10481 Filed 5-10-88; 8:45 am]
BILLING CODE 4160-01-M

[Docket No. 88M-0107]

Allergan Optical; Premarket Approval of Duraclean™ Daily Cleaner

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Allergan Optical, Irvine, CA, for premarket approval, under the Medical Device Amendments of 1976, of Duraclean™ Daily Cleaner for use to clean rigid gas permeable contact lenses before rinsing and disinfection. After reviewing the recommendation of the Ophthalmic Devices Panel, FDA's Center for Devices and Radiological Health (CDRH) notified the applicant by letter of March 9, 1988, of the approval of the application.

DATE: Petitions for administrative review by June 10, 1988.

ADDRESS: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: David M. Whipple, Center for Devices and Radiological Health (HFZ-460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7940.

SUPPLEMENTARY INFORMATION: On May 21, 1987, Allergan Optical, Irvine, CA 92715, submitted to CDRH an application for premarket approval of Duraclean™ Daily Cleaner for use to clean rigid gas permeable contact lenses before rinsing and disinfection.

On November 17, 1987, the Ophthalmic Devices Panel, an FDA advisory committee, reviewed and recommended approval of the application. On March 9, 1988, CDRH approved the application by a letter to the applicant from the Director of the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

A copy of all approved labeling is available for public inspection at CDRH—contact David M. Whipple (HFZ-460), address above.

The labeling of Duraclean™ Daily Cleaner states that the solution is indicated for use to clean rigid gas permeable contact lenses before rinsing and disinfection. Manufacturers of rigid gas permeable contact lenses that have been approved for marketing are

advised that whenever CDRH publishes a notice in the Federal Register of the approval of a new solution for use with an approved rigid gas permeable contact lens, the manufacturer of each lens shall correct its labeling to refer to the new solution at the next printing or at such other time as CDRH prescribes by letter to the applicant.

Opportunity for Administrative Review

Section 515(d)(3) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e(d)(3)) authorizes any interested person to petition, under section 515(g) of the act (21 U.S.C. 360e(g)), for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under Part 12 (21 CFR Part 12) of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under § 10.33(b) (21 CFR 10.33(b)). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the Federal Register. If FDA grants the petition, the notice will state the issue to be reviewed, the form of review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before June 10, 1988, file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h), 90 Stat. 554-555, 571 (21 U.S.C. 360e(d), 360(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).